

ICOS Rec'd PCT/PTO 30 SEP 2005

Docket No. 21478USWO (C038435/0187441)

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	10/533,858	).	Examiner:	Not yet assigned
Filed:	May 5, 2005	)	Art Unit:	Not yet assigned
For:	NOVEL NUTRACEUTICAL COMPOSITIONS COMPRISING	)		
	EPIGALLOCATECHIN GALLATE	)		

New York, New York September 27, 2005

# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants wish to make of record the following documents (clean copies and a Form PTO-1449 listing the documents are enclosed):

# **U.S. PATENT DOCUMENTS**

	<u>Document No.</u>	<u>Date</u>
A4	US 2002/0082298 A1	6/27/2002
A5	5,599,835	2/4/1997
<b>A</b> 6	5,714,519	2/3/1998

## **FOREIGN PATENT DOCUMENTS**

	<b>Document No.</b>	<u>Date</u>	Country
B6	EP 1 177 789 A2	2/6/2002	Europe

# **OTHER DOCUMENTS**

- C.B.Andersen et al., "The Effect Of Coenzyme Q<sub>10</sub> On Blood Glucose And Insulin Requirement In Patients With Insulin Dependent Diabetes Mellitus," Molec. Aspects Med., vol. 18, pp. s307-s309 (1997).
- C5 R.C. Eason et al., "Lipoic Acid Increases Glucose Uptake By Skeletal Muscles Of Obese-Diabetic ob/ob Mice," <u>Diabetes, Obesity and Metabolism</u>, vol. 4, pp. 29-35 (2002).
- C6 J.G. Eriksson et al., "The Effect Of Coenzyme Q<sub>10</sub> Administration On Metabolic Control In Patients With Type 2 Diabetes Mellitus," BioFactors, vol. 9, pp. 315-318 (1999).
- C7 M. Eto et al., "Lowering Effect Of Pantethine On Plasma β-Thromboglobulin And Lipids In Diabetes Mellitus," Artery, vol. 15, no. 1, pp. 1-12 (1987).
- C8 J.L. Evans and I.D. Goldfine, "α-Lipoic Acid: A Multifunctional Antioxidant That Improves Insulin Sensitivity In Patients With Type 2 Diabetes," Diabetes Technol. & Ther., vol. 2, no. 3, pp. 401-413 (2000).
- C9 Y. Hara and M. Honda, "The Inhibition Of α-Amylase By Tea Polyphenols," Agric. Biol. Chem., vol. 54, no. 8, pp. 1939-1945 (1990).
- C10 M. Heim *et al.*, "Phytanic Acid, A Natural Peroxisome Proliferator-Activated Receptor Agonist, Regulates Glucose Metabolism In Rat Primary Hepatocytes," FASEB J., vol. 16, pp. 718-720 (2002).
- C11 Y. Kobayashi et al., "Green Tea Polyphenols Inhibit The Sodium-Dependent Glucose Transporter Of Intestinal Epithelial Cells By A Competitive Mechanism," <u>J. Agric. Food Chem.</u>, vol. 48, pp. 5618-5623 (2000).
- C12 D. Manzella et al., "Chronic Administration Of Pharmacologic Doses Of Vitamin E Improves The Cardiac Autonomic Nervous System In Patients With Type 2 Diabetes," Am. J. Clin. Nutr., vol. 73, pp. 1052-1057 (2001).

- C13 R. Miccoli et al., "Effects Of Pantethine On Lipids And Apolipoproteins In Hypercholesterolemic Diabetic And Non Diabetic Patients," Cur. Ther. Res., vol. 36, no. 3, pp. 545-549 (1984).
- C14 M. Shimizu et al., "Regulation Of Intestinal Glucose Transport By Tea Catechins," BioFactors, vol. 13, pp. 61-65 (2000).
- C15 R.B. Singh et al., "Effect Of Hydrosoluble Coenzyme Q10 On Blood Pressures And Insulin Resistance In Hypertensive Patients With Coronary Artery Disease," J. Hum. Hypertens., vol. 13, pp. 203-208 (1999).
- C16 G.F. Watts et al., "Coenzyme Q<sub>10</sub> Improves Endothelial Dysfunction Of The Brachial Artery In Type II Diabetes Mellitus," <u>Diabetologia</u>, vol. 45, pp. 420-426 (2002).
- C17 A.W. Zomer et al., "Pristanic Acid And Phytanic Acid: Naturally Occurring Ligands For The Nuclear Receptor Peroxisome Proliferator-Activated Receptor α," J. Lipid Res., vol. 41, pp. 1801-1807 (2000).

The Examiner's independent consideration of all of these documents and their relevance before issuance of the first official action is respectfully requested. The Examiner is also requested to initial and return a copy of the accompanying forms PTO-1449 to evidence such consideration.

Copies of all the above documents, other than U.S. Patent Documents, are provided. See MPEP § 609(III)(A)(2)(A) (8<sup>th</sup> Ed., Rev. 2, May 2004, p. 600-128); See also 1276 OG 55 (August 5, 2003) (Waiving the requirement under Rule 98(a)(2)(1) to provide a copy of each cited U.S. patent document for any application filed after June 30, 2003.).

This Supplemental Information Disclosure Statement is being filed in accordance with the provisions under 37 C.F.R. §1.97(b)(3), before the mailing of the first Office action on the merits. Accordingly, no fee is believed to be due. If, however,

a fee is due, please charge the same to Deposit Account No. 02-4467. A duplicate copy of this sheet is enclosed.

If the Examiner has any questions regarding this paper, please contact the undersigned attorney.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Mail Stop Amendment, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on September 27, 2005.

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Respectfully submitted,

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Form PTO-1449 (Rev. )

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PA	AND TRADEMARK OFFICE

ATTY. DOCKET NO.: 21478USWO (C038435/187441)

SERIAL NO.: 10/533,858

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

Daniel RAEDERSTORFF et al.

FILING DATE:

APPLICANT(S):

GROUP:

May 5, 2005

Not yet assigned

### **U.S. PATENT DOCUMENTS**

Examiner Initial	Cite No.	U.S. Patent Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	A4	US 2002/0082298 A1	6/27/2002	Fluehmann et al.			
	A5	5,599,835	2/4/1997	Fischer			
	A6	5,714,519	2/3/1998	Cincotta et al.			

#### FOREIGN PATENT DOCUMENTS

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### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	C4	C.B.Andersen et al., "The Effect Of Coenzyme Q <sub>10</sub> On Blood Glucose And Insulin Requirement In Patients With Insulin Dependent Diabetes Mellitus," Molec. Aspects Med., vol. 18, pp. s307-s309 (1997).				
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EXAMINE	R	DATE CONSIDERED				

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Form PTO-1449 (Rev. )	U.S ARTMENT OF COMMERCE PATE AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 21478USWO (C038435/187441)	SERIAL NO.: 10/533,858	
	ISCLOSURE STATEMENT APPLICANT	APPLICANT(S): Daniel RAEDERSTORFF et al.		
(Use sever	ral sheets if necessary)	FILING DATE: May 5, 2005	GROUP: Not yet assigned	

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### FOREIGN PATENT DOCUMENTS

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		Document Number	Date	Country	Class	Subclass	Yes	No
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